Portland VA Medical Center

Education in the Emergency Use of Investigational Devices

Emergency Use of Investigational Devices

- An investigator and/or physician must adhere to many procedures regarding an emergency use of an unapproved medical device.
- The food and drug administration (FDA) recognizes that emergencies may arise where an unapproved investigational device may offer the only possible life-saving alternative, but an FDA awarded investigational device exemption (IDE) does not exist, or the proposed use is not approved under an existing IDE, or the physician or institution is not approved under the IDE.
- Using its enforcement discretion, the FDA has not objected if a physician chooses to use an unapproved device in an emergency situation, provided that the physician later justifies to the FDA that an emergency actually existed.

Emergency Use of Investigational Devices (Cont'd)

- What is an **investigational device**?
  - A device that is the object of an investigation [21CFR812.3(g)].
- What does the FDA consider to be an **investigation**?
  - A clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device [21CFR812.3(h)]
- What is an **unapproved medical device**?
  - A device that is used for a purpose or condition for which the device requires, but does not have an approved application for pre-market approval, i.E. The device is not FDA approved for marketing.

Emergency Use of Investigational Devices (Cont'd)

- What are the requirements for emergency use of a medical device?
- **Note:** all of the following **three** requirements must be met for justification of emergency use.
  - A patient is in a life-threatening condition that needs immediate treatment;
  - There is no generally acceptable alternative available for treating the patient; and
  - Sufficient time is not available to obtain prior FDA approval through existing procedures, prior to using the device of the immediate need.

Emergency Use of Investigational Devices (Cont'd)

- What does the FDA expect of a physician, regarding the decision to use an investigational device in an emergency situation?
- The FDA expects that a p**hysician**:
  - Determined whether all three requirements for emergency use have been met;
  - Assessed the potential benefits from the unapproved use of the device;
  - Had substantial reason to believe that benefits will exist;
  - Did not make the decisions for "emergency" use in advance of the time of treatment, solely on the expectation that the IDE approval procedures may require more time than is available; and
  - Exercised reasonable foresight with respect to potential emergencies and made appropriate arrangements under the IDE procedures far enough in advance to avoid creating a situation in which such arrangements are impracticable.

Emergency Use of Investigational Devices (Cont'd)

- When an unapproved investigational device is used in an emergency situation, the device developer must notify the center for devices and radiological health after the shipment of the device to the physician has been made.

Emergency Use of Investigational Devices (Cont'd)

- What subject protection measures does the FDA expect a physician to follow when using an investigational device in an emergency situation?
- The FDA expects that a physician will:
  - Obtain an independent assessment by an uninvolved physician;
  - Obtain informed consent from the patient or the patient's legal representative;
  - Notify the PVAMC chief of staff;
  - Notify the institutional review board; and
  - Obtain authorization from the IDE holder, if an approved IDE exists for the device.

Emergency Use of Investigational Devices (Cont'd)

- What procedures must a physician follow after an unapproved investigational device has been used in an emergency situation?
- The physician must:
  - Report the use of the unapproved medical device to the IRB within five days of usage and otherwise comply with provisions of the IRB regulations;
  - Evaluate the need for the device in the future, and if future use is likely, obtain IRB approval and an approved IDE for future use; and
  - Notify the sponsor of the emergency use and if the device does have an IDE or if an IDE does not exist, notify the FDA of the emergency use and provide the FDA with a written summary of the conditions constituting the emergency, subject protection measures and results.

Summary

- This education module has covered the key aspects specific to the emergency use of investigational devices at the PVAMC.
- If you have any questions regarding the material in this training module, please do not hesitate to contact:

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